

This is an official

CDC Health Advisory

Distributed via the South Carolina Health Alert Network
April 15, 2008, 17:00 EDT (05:00 PM EDT)

CDC Alert on Adverse Effects Associated with Consuming “Total Body Formula” and “Total Body Mega Formula”

The Centers for Disease Control and Prevention is working collaboratively with state health departments, the American Association of Poison Control Centers, and the U.S. Food and Drug Administration (FDA) on reports of adverse health effects following consumption of the dietary supplement “Total Body Formula,” and “Total Body Mega Formula” manufactured in the USA exclusively for Total Body Essential Nutrition, Inc. This dietary supplement has been found by FDA to contain hazardous levels of selenium (up to 200 times the label value) and chromium (up to 17 times the label value).

An FDA press release on April 9, 2008 detailed information regarding the level of selenium in the product (<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01818.html>). FDA is advising consumers to stop using “Total Body Formula” in flavors Tropical Orange and Peach Nectar and “Total Body Mega Formula” in the Orange/Tangerine flavor and discard them by placing them in a trash receptacle outside of the home. “Total Body Formula” products are sold in eight-ounce and 32-ounce plastic bottles. “Total Body Mega Formula” is sold in 32-ounce plastic bottles. Products with the following lot numbers should be discarded: Total Body Tropical Orange with lot numbers 4016801, 4024801 and 4031801; Total Body Peach Nectar with lot numbers 4016802 and 4031802; and Total Body Mega Orange/Tangerine with lot number 4031803.

As of April 15, 2008, 128 adverse reactions¹ have been reported from Florida, Georgia, Kentucky, North Carolina, Pennsylvania, Tennessee, Texas and Virginia health departments. The American Association of Poison Control Centers and the FDA report additional exposures in other states.

Total Body Essential Nutrition, Inc reportedly distributed this product to 16 states (Alabama, California, Florida, Georgia, Kentucky, Louisiana, Michigan, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, and Virginia.) Total Body Essential Nutrition also sells its products over the Internet (www.totalbodyteam.com.)

Clinical description of selenium toxicity

Excessive intake of selenium is known to cause the following symptoms: significant hair loss, muscle cramps, diarrhea, joint pain, fatigue, loss of finger nails and blistering skin.

Clinical description of chromium toxicity

Excessive intake of chromium may result in the following symptoms: renal failure, elevated hepatic enzymes, thrombocytopenia, hemolysis, changes in thought processes, gastrointestinal disorders, chest pain, erythema/flushing/rash, dizziness, headache, agitation, and rhabdomyolysis.

Case definition

Individuals presenting with two or more of the following symptoms that occurred within two weeks of ingesting a dietary supplement manufactured in the USA exclusively for Total Body Essential Nutrition, Inc: hair loss,

¹ Numbers may vary from other posted Health Advisories on this subject. Updated numbers of cases and names of affected states received from CDC 4/15/2008.

muscle or joint pains, fingernail discoloration or changes, headache, foul breath, weakness, gastrointestinal symptoms (such as nausea, vomiting, diarrhea or abdominal pain), rash, oliguria/anuria or abnormal renal function tests, jaundice or abnormal liver function tests, anemia or hematological changes.

Reporting

CDC requests that consumers and clinicians who encounter patients with symptoms consistent with selenium and/or chromium poisoning report these cases to their local Poison Control Center (PCC) at 1-800-222-1222. Medical personnel are available at PCCs to provide specific medical management advice and will make appropriate referral to state and local health authorities.

Health care professionals and consumers are also encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

DHEC Contact Information for Reportable Diseases and Reporting Requirements

Reporting of outbreaks/clusters of cases is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2006 List of Reportable Conditions available at: http://www.scdhec.gov/health/disease/docs/reportable_conditions.pdf.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2008

Mail or call reports to the Epidemiology Office in each Public Health Region.

Region 1

Anderson, Oconee

220 McGee Road
Anderson, SC 29625
Phone: (864) 260-4358
Fax: (864) 260-5623
Nights / Weekends: 1-866-298-4442

Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda

1736 S. Main Street
Greenwood, SC 29646
Phone: 1-888-218-5475
Fax: (864) 942-3690
Nights / Weekends: 1-800-420-1915

Region 2

Greenville, Pickens

PO Box 2507
200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 282-4139
Fax: (864) 282-4373
Nights / Weekends: 1-800-993-1186

Cherokee, Spartanburg, Union

PO Box 4217
151 E. Wood Street
Spartanburg, SC 29305-4217
Phone: (864) 596-2227, x- 210
Fax: (864) 596-3443
Nights / Weekends: 1-800-993-1186

Region 3

Chester, Lancaster, York

PO Box 817
1833 Pageland Highway
Lancaster, SC 29721
Phone: (803) 286-9948
Fax: (803) 286-5418
Nights / Weekends: 1-866-867-3886

Region 3 (continued)

Fairfield, Lexington, Newberry, Richland

2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: 1-888-554-9915

Region 4

Clarendon, Kershaw, Lee, Sumter

PO Box 1628
105 North Magnolia Street
Sumter, SC 29150
Phone: (803) 773-5511
Fax: (803) 775-9941
Nights/Weekends: 1-877-831-4647

Chesterfield, Darlington, Dillon, Florence,

Marlboro, Marion
145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 660-8145

Region 5

Bamberg, Calhoun, Orangeburg

PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 533-7199
Fax: (803) 533-7134
Nights / Weekends: (803) 954-8513

Aiken, Allendale, Barnwell

1680 Richland Avenue, W. Suite 40
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 643-8386
Nights / Weekends: (803) 827-8668 or
1-800-614-1519

Region 6

Georgetown, Horry, Williamsburg

2830 Oak Street
Conway, SC 29526-4560
Phone: (843) 365-3126, x-138 or x-174
Fax: (843) 365-3153
Nights / Weekends: (843) 381-6710

Region 7

Berkeley, Charleston, Dorchester

4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 746-3806
Fax: (843) 746-3851
Nights / Weekends: (843) 219-8470

Region 8

Beaufort, Colleton, Hampton, Jasper

219 S. Lemacks Street
Walterboro, SC 29488
Phone: (843) 549-1516, x-214
Fax: (843) 549-6845
Nights / Weekends: 1-800-614-4698

DHEC Bureau of Disease Control

Division of Acute Disease Epidemiology

1751 Calhoun Street
Box 101106
Columbia, SC 29211
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902



www.scdhec.gov

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action.

Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.